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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,597	08/10/2001	Fady Malik	CYTOP018/1057	8190

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

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DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/927,597	Applicant(s) MALIK ET AL.	
	Examiner David J. Steadman	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Application Status

- [1] Claims 1-15 are pending in the application.
- [2] Receipt of an Information Disclosure Statement (IDS) filed as Paper No. 4 is acknowledged. The references cited therein will be considered by the examiner and a copy of the IDS will be returned in a subsequent Office action.
- [3] It is noted that the claims have been grouped according to the specification's disclosure that SEQ ID NO:6, 8, 10, 12, and 14 are fragments of SEQ ID NO:2 (see pages 7 and 8 of the instant specification) and a visual inspection of the amino acid sequence of SEQ ID NO:2 and 4, which indicates that these amino acid sequences are different and therefore structurally distinct.

Election/Restrictions

- [4] Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claim(s) 1-7, 14, and 15, drawn to an isolated nucleic acid encoding SEQ ID NO:2, 6, 8, 10, 12, and 14, an isolated nucleic acid comprising SEQ ID NO:1, 5, 7, 9, 11, and 13, an expression vector, and a host cell, classified in class 435, subclass 325.
 - II. Claim(s) 1-7, 14, and 15, drawn to an isolated nucleic acid encoding SEQ ID NO:4, an isolated nucleic acid comprising SEQ ID NO:3, an expression vector, and a host cell, classified in class 435, subclass 325.
 - III. Claim(s) 8-10, drawn to an isolated polypeptide of SEQ ID NO:2, 6, 8, 10, 12, and 14 and variants thereof, classified in class 435, subclass 196.
 - IV. Claim(s) 8-10, drawn to an isolated polypeptide of SEQ ID NO:4 and variants thereof, classified in class 435, subclass 196.
 - V. Claim(s) 11-13, drawn to a method for screening for modulators of SEQ ID NO:2, 6, 8, 10, 12, and 14 and variants thereof, classified in class 435, subclass 19.

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VI. Claim(s) 11-13, drawn to a method for screening for modulators of SEQ ID NO:4 and variants thereof, classified in class 435, subclass 19.

[5] The inventions are distinct, each from the other because:

[6] The nucleic acids of Groups I and II are structurally distinct, encode structurally distinct polypeptides and neither of the nucleic acids of Groups I and II would render the other obvious to one of ordinary skill in the art.

[7] The polypeptides of Groups III and IV are structurally distinct and neither of the polypeptides of Groups III and IV would render the other obvious to one of ordinary skill in the art.

[8] The methods of Groups V and VI are independent as they utilize structurally different products.

[9] The nucleic acids of Group(s) I and II and the polypeptide(s) of Group(s) III and IV each comprises a chemically unrelated structure capable of separate manufacture, use and effect. The polynucleotide(s) of Group(s) I and II have other utility besides encoding polypeptides such as being used as a hybridization probe and the polypeptide(s) of Group(s) III and IV can be made by another method such as purification from the natural source or chemical synthesis.

[10] The nucleic acids of Group(s) I and II are unrelated to the method(s) of Group(s) V and VI as they are neither used nor made by the method(s) of Group(s) V and VI.

[11] The polypeptide(s) of Group(s) III and IV and the methods of Groups V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide(s) of Group(s) III and IV can be used as antigens for the production of antibodies.

[12] MPEP § 803 sets forth two criteria for restricting between patentably distinct inventions – 1) the inventions must be independent or distinct and 2) there must be a serious burden on the examiner. MPEP § 803 states, "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate

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status in the art, or a different field of search as defined in MPEP § 808.02". Because the inventions of Groups I-VI are distinct for the reasons given above and/or have separate classification and each of the inventions requires a separate patent and non-patent literature and/or sequence search, restriction for examination purposes is proper.

[13] It is noted that claims 1-15 will be examined only to the extent the claims read on the elected subject matter.

[14] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[15] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

DS 07/02/03